ORAL CAVITY AND OROPHARYNX OUTCOMES

By David Tsen, MD

Oral cavity and orophaynx are relatively unusual areas where cancers can arise to cause severe functional destruction resulting in social stigma. Various cancer societies have estimated that in the United States yearly, approximately 30,000-40,000 new cases of cancer will ravage this part of the body, thereby making up 3-5% of total cancers diagnosed. Oral cavity is considered to be that part of the body from behind the mucous lining of the lip to the demarcation just before the tonsils. Oropharynx starts at the tonsil, to include the soft palate and base of tongue, and ends at the transition to the epiglottis. Because of an approximate 50% overall five year national mortality rate for cancers in these two regions, the relatively small number for these cancers still command great resourcefulness and resolution from the health care system and the afflicted patients in order to conquer the cancer's morbid destructiveness.

Innovis Health Cancer Center has demonstrated consistent leadership and innovation in the field of head and neck cancer in general and oral and oropharyngeal cancers in particular. Our success is therefore reflected in the data that is presented in this annual report.

Diagnosis

As demonstrated in **Figure 1**, 145 cases of oral and oropharyngeal primary cancers have been treated at our facility from 2001-2008. The most common organ affected with cancer in the oral cavity is the anterior tongue (gum and other mouth is aggregated data of several other parts of the oral cavity). Tonsil cancers are the more commonly occurring subset of oropharyngeal cancers.

FIGURE 1:
Primary Sites
Included in Report

	Number of Cases at Innovis Health 2001-2008
ORAL CAVITY	
Tongue (anterior 2/3)	44
Floor of Mouth	19
Gum & Other Mouth	47
OROPHARYNX	
Tonsil	25
Other	10
TOTAL Number of Cases	**145**

The typical symptoms at presentation are mass in the mouth or back of the throat region (68%), followed almost equally by neck mass (15%) and sore throat (12%). We have noted also that 71% of these patients are smokers and 39% are alcohol users, trends that are consistent with literature.

SYMPTOMS:
Lesion, mass, soreness in mouth – 68%
Neck mass – 12%
Sore throat – 12%

SMOKING HISTORY:
71% of patients at Innovis Health were current or former smokers.

ALCOHOL HISTORY:
39% of patients at Innovis Health were current or former alcohol users.

Figure 2 indicates that the age distributions from our Center are similar to data from the National Cancer Data Base (NCDB), although in our small number we have seen lower percentages in the middle age group (age 40-49) and the young retirement group (age 60-69).

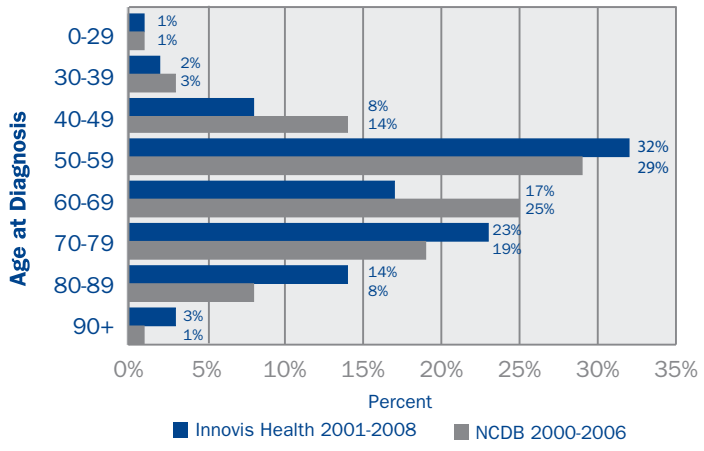


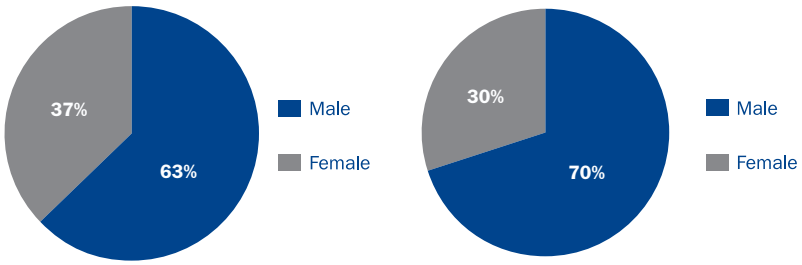
FIGURE 2:
Age at Diagnosis of Oral Cavity & Oropharynx Cancer

Innovis Health vs. NCDB

As **Figure 3** indicates, a majority of the cancers are male in both our population and the national data, which is simply reflective of the higher percentage of tobacco and alcohol abusers among the males.

FIGURE 3:

Gender of Oral Cavity and Oropharynx Cancer



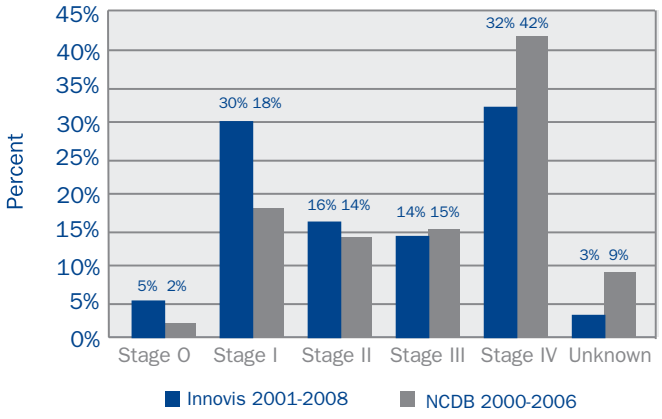
Innovis Health
2001-2008

NCDB
2000-2006

Figure 4 shows that we have treated a substantially higher percentage of early stage cancers than the rest of the nation, a trend that is reflective of the higher health consciousness of the Upper Midwest region.

FIGURE 4:
Stage at Diagnosis of Oral Cavity & Oropharynx Cancer

Innovis Health vs. NCDB



Treatment

Innovis Health and its predecessor Dakota Clinic have been early regional leaders in championing a team collaboration approach for treatment of head and neck cancers, standard among academic tertiary care institutions. Our data, as shown in **Figure 5**, reflects this team approach. The trend toward more surgery for Innovis (45%) versus the nation (30%) is consistent with our seeing a larger number of early stage cancers, which are usually treated best surgically, as demonstrated in **Figure 6**. Innovis is in line with the national trend to increasingly treat the advanced cancers (Stages III and IV) with radiation and chemotherapy only (19% vs 21% in Figure 5) or with surgery as a salvage (9% vs 8%). Innovations in more effective new chemotherapy agents, such as the taxols, in conjunction with better cancer-killing capabilities of chemotherapy drugs that sensitize the cancer cells to the therapeutic effect of radiation, such as cis-platinum or cis-platinum/5-fluorouricil combination, have fueled the drive to spare advanced cancer patients the debilitating effect of primary cancer surgery. The trade-off is to accept the high toxicity of chemotherapy followed by radiation or of concurrent chemotherapy and radiation. Surgery is then reserved for salvage of unresponsive cases or to "clean up" residual cancers, usually in the metastasis to the neck. This trend toward treating advanced stage disease (Stage IV) is reflective of the data presented in **Figure 6**, in that more cases of Stage IV disease are treated in Innovis with RT + Chemo and Surgery + RT + Chemo (28 total) versus single modality alone, whether it be surgery (3) versus radiation (3), or versus the traditional regimen of destructive surgery followed by adjuvant radiation therapy (10). In the case of Stage III disease, the literature supports equal efficacy of several single modality therapies, which is then reflective of the equal distribution of Stage III disease using various treatment modalities at our institution.

Innovations in more effective new chemotherapy agents have fueled the drive to spare advanced cancer patients the debilitating effect of primary cancer surgery.

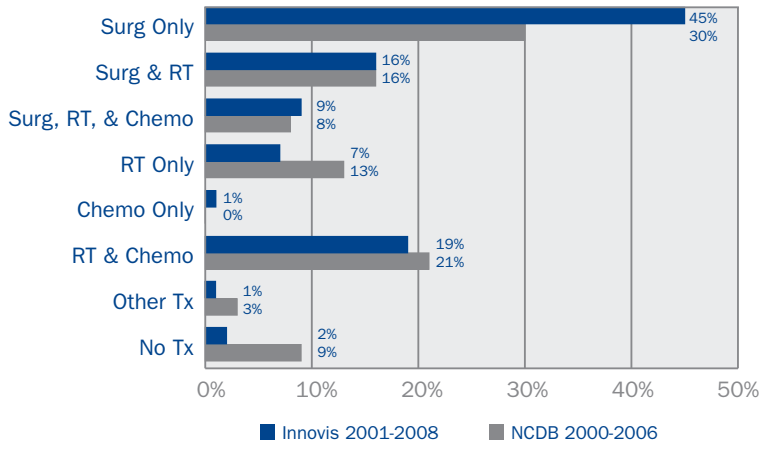


FIGURE 5:
Treatment of Oral Cavity and Oropharynx Cancer

Innovis Health vs. NCDB

FIGURE 6:
Treatment *by Stage* of Oral Cavity and Oropharynx Cancer

Innovis Health
2001-2008
(Number of Patients)

FIRST COURSE OF TREATMENT	STAGE 0	STAGE I	STAGE II	STAGE III	STAGE IV	UNKNOWN	TOTAL
Surg alone	7	37	16	2	3	0	65
Surg + RT	0	4	3	5	10	1	23
RT alone	0	1	2	4	3	1	11
RT + Chemo	0	1	2	5	20	0	28
Surg + RT + Chemo	0	0	1	4	8	0	13
Other Tx	0	0	0	0	3	2	5
TOTAL	**7**	**43**	**24**	**20**	**47**	**4**	**145**

Overall, 74% of oral cavity and oropharynx patients are treated with surgery at some point of their treatment at Innovis, as opposed to 52% for radiation therapy and 28% for chemotherapy. Since Innovis first introduced intensity modulated radiation therapy (IMRT) to this region in 2003, IMRT has become the main mode of delivering radiation to all of our head and neck cancer patients.

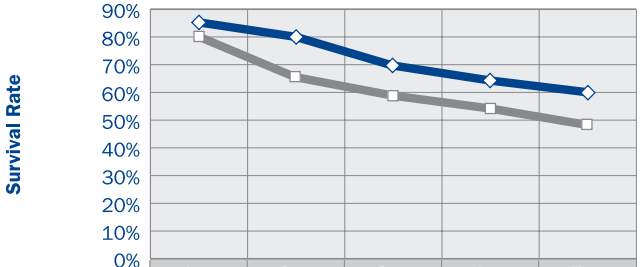
SURGERY:
Overall, 74% of patients at Innovis Health received surgery.

CHEMOTHERAPY:
Overall, 28% of patients at Innovis Health received chemotherapy—the majority with Stage III or IV disease.

RADIATION THERAPY:
Overall, 52% of patients at Innovis received radiation therapy; since 2003 Intensity Modulated Radiation Therapy (IMRT) has become the main modality for delivering radiation.

Survival

Our innovation and resourcefulness has resulted in five year overall survival data that surpasses the national average, as demonstrated in **Figure 7**. This survival advantage may be reflective of the small number of our treatment population, but the trend is evident at one year post treatment and continues beyond 5 years, when such cancers are considered to be in complete remission.

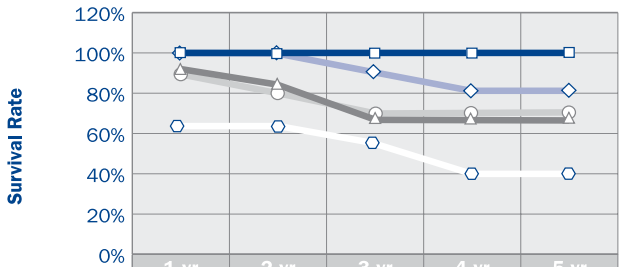


	1 yr	2 yr	3 yr	4 yr	5 yr
Innovis 2001-2004	85%	80%	70%	64%	60%
Natl. 1998-2001	80%	66%	59%	54%	49%

FIGURE 7:
Five Year *Overall* Observed Survival of Oral Cavity and Oropharynx Cancer

Innovis Health vs. NCDB

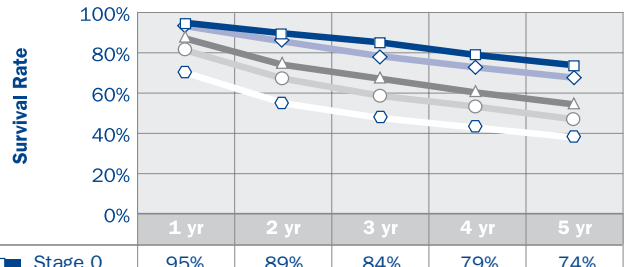
Figures 8 and **9** break the survival statistics down by stage of disease. Our Center's data consistently shows that the survival of all stages of oral and oropharyngeal cancers matches or surpasses the national survival percentages. The results are especially evident for the Stages 0 through III cancers, while those of Stage IV disease approaches that of national survival rate of 39% at 5 years.



	1 yr	2 yr	3 yr	4 yr	5 yr
Stage 0	100%	100%	100%	100%	100%
Stage I	100%	100%	92%	81%	81%
Stage II	92%	84%	67%	67%	67%
Stage III	90%	80%	70%	70%	70%
Stage IV	63%	63%	56%	40%	40%

FIGURES 8 AND 9
Five Year Observed Survival By Stage for Oral Cavity and Oropharynx Cancer

Innovis Health 2001-2004



	1 yr	2 yr	3 yr	4 yr	5 yr
Stage 0	95%	89%	84%	79%	74%
Stage I	94%	86%	79%	73%	68%
Stage II	88%	75%	67%	60%	55%
Stage III	81%	67%	59%	54%	49%
Stage IV	71%	55%	48%	43%	39%

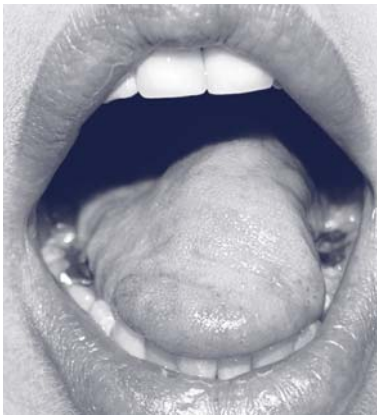
NCDB 1998-2001

Figure 10 shows the excellent functional and aesthetic results of one of our patients with early stage anterior tongue cancer treated with surgery (hemiglossectomy and conservative neck dissection) followed with adjuvant radiation therapy.

FIGURE 10

Photo Left:
Right hemiglossectomy

Photo Right:
Right supraomohyoid neck dissection and tracheotomy



Innovis Health Cancer Center's data consistently shows that the survival of all stages of oral and oropharyngeal cancers matches or surpasses the national survival percentages.

What is lacking in the Innovis data is a tabulation of the biological markers affecting survival of head and neck cancers. In particular, recent literature has suggested positive effects on survival of cancers exhibiting markers for human papilloma virus (HPV 16 and 18) and negative effects of epidermal growth factor. While we have begun to test HPV in a majority of head and neck cancer specimens in the last three years, this data is not presented in this report. Our preliminary findings correlate to the national data, in that HPV positive patients, even those with advanced tonsil cancers, have a better response to any cancer therapy conferring better survival than non-HPV cancers, regardless of stage.

Conclusion

In summary, our team approach to treatment of head and neck cancers at Innovis Health Cancer Center has translated to our patients' excellent results when compared to the national data.